

Substitute for form 1449A/PTO (modified)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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JUL 10 2006

Page 1 of 2

Application Number **10/596,836**Filing Date **December 10, 2004**First Named Inventor **Capecci, John T.**Confirmation Number **1181**Attorney Case Number **59029US004**

U.S. Patent Documents

| Exam. Init.* | Cite No. | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|-----------------|-------------|----------------------------------|--------------------------------|----------------------------------------------------|---------------------------------------------------------------------------------|
| | | Doc. Number-(Kind Code if Known) | | | |
| /CRL/ | A1 | US- 5,041,529 | 8/20/1991 | Shinoda et al. | |
| | A2 | US- 5,302,693 | 4/12/1994 | Stricker et al. | |
| | A3 | US- 5,569,450 | 10/29/1996 | Duan et al. | |
| | A4 | US- 5,618,911 | 4/08/1997 | Kimura et al. | |
| | A5 | US- 5,714,618 | 2/03/1998 | Kimura et al. | |
| | A6 | US- 5,871,771 | 2/16/1999 | Zierenberg et al. | |
| | A7 | US- 6,111,033 | 8/29/2000 | Loughman et al. | |
| | A8 | US- 6,126,919 | 10/03/2000 | Stefely et al. | |
| | A9 | US- 6,264,970 | 7/24/2001 | Hata et al. | |
| | A10 | US- 6,416,742 | 9/07/2002 | Stefely et al. | |
| | A11 | US- 2002/164290 | 11/07/2002 | Stefely et al. | |
| | A12 | US- 2002/173496 | 11/21/2002 | Biggadike | |
| | A13 | US- 2004/247561 | 4/24/2003 | Seo et al. | |
| V | A14 | US- 2004/253195 | 12/16/2004 | Seo et al. | |
| /CRL/ | | US- | | | |

Foreign Patent Documents

| Exam. Init.* | Cite No. | Foreign Patent Document | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | Translation (Check if yes) |
|-----------------|-------------|-------------------------|----------------------------|--------------------------------|----------------------------------------------------|---------------------------------------------------------------------------------|-------------------------------|
| | | Ctry. Code | Number-KindCode (if known) | | | | |
| /CRL/ | B1 | JP | 9059218 | 3/04/1997 | Shimadzu Corp. | | Yes |
| /CRL/ | B2 | JP | 9124778 | 5/13/1997 | Shimadzu Corp. | Abstract Only | |
| /CRL/ | B3 | WO | 94/21229 | 9/29/1994 | Minnesota Mining | | |
| /CRL/ | B4 | WO | 03/033592 | 4/24/2003 | Samyang Corp. | | |
| /CRL/ | B5 | WO | 03/033593 | 4/24/2003 | Samyang Corp. | | |

OTHER DOCUMENTS

| Exam. Init.* | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | Translation (Check if yes) |
|-----------------|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| /CRL/ | C1 | H. Fukazaki et al., "Synthesis of Copoly (D,L-Lactic Acid) with Relatively Low Molecular Weight and In Vitro Degradation," <i>Eur. Polym. J.</i> , 25, 1019-1026 (1989) | |

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|---------------------------------|-----------------------------|
| *Examiner: /Christopher R. Lea/ | Date Considered: 05/21/2009 |
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| Page 2 of 2 | | Attorney Case Number | 59029US004 |

OTHER DOCUMENTS

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|-----------------|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| /CRL/ | C2 | A. Carrio et al., "Preparation and degradation of surfactant-free PLAGA microsphere," <i>J. Controlled Release</i> , 37, 113-121 (1995) | |
| /CRL/ | C3 | P.P. DeLuca et al., "Biodegradable Polyesters for Drug and Polypeptide Delivery," <i>Polymeric Delivery Systems</i> ; ACS; Chapter 4, 53-77 (1993) | |
| /CRL/ | C4 | B. Wichert et al., "Low molecular weight PLA: a suitable polymer for pulmonary administered microparticles?". <i>J. Microencapsulation</i> , 10, 195-207 (1993) | |
| /CRL/ | C5 | J.W. Tom et al., "Precipitation of Poly(L-lactic acid) and Composite Poly(L-lactic acid)-Pyrene Particles by Rapid Expansion of Supercritical Solutions; <i>J. Supercritical Fluids</i> , 7, 9-29 (1994) | |
| /CRL/ | C6 | R. Wada et al., "New biodegradable oligoesters for pharmaceutical application," <i>J. Biomater Sci., Polym. Ed.</i> , 7, 715-725 (1996) | |
| /CRL/ | C7 | M. Dittrich, "Purification of biodegradable polymers and oligomers of aliphatic hydroxyl acids", Abstract of Czech Patent No. CZ 278181 (Sept. 15, 1993) Abstract only: CA122(16):188468y. | |
| /CRL/ | C8 | D. Duan et al., "Oligomeric Lactic Acids as Solubilizing Aids for HFA-Based Metered Dose Inhalers," Biomaterials Technology Center, 3M Corporation, 3M Pharmaceuticals (11/98) | |
| /CRL/ | C9 | D. Duan et al., "Novel Dispersing Aids for Hydrofluoroalkane-Based Metered Dose Inhalers," Biomaterials Technology Center, 3M Corporation, 3M Pharmaceuticals (11/98) | |
| /CRL/ | C10 | C. Leach et al., "Metabolism, Distribution, and Toxicity of Oligomeric Lactic Acids Used in Pulmonary Drug Delivery," Biomaterials Technology Center, 3M Corporation, 3M Pharmaceuticals (November 1998) | |
| /CRL/ | C11 | J. Stefely et al., "Design and Utility of a Novel Class of Biocompatible Excipients for HFA-Based MDIs," Respiratory Drug Delivery VII, Palm Harbor at Tarpon Springs, FL, 5/14-18, 2000 | |

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|------------------|------------|
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